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11/28/99

MINUTES OF A FEEDBACK MEETING

October 8, 1999  
10:00am - 11:00am  
9201 Corporate Blvd., Rockville, MD  
Conference Room S400

**Warner-Lambert Company**

Paul Okarma, Ph.D., Director, Regulatory Affairs  
Lori Kumar, Director, R&D, Oral Care  
Michael Loughner, Manager, Public Affairs  
Scott Harper, Ph.D., Technology Development, Oral Care  
Lynn Lee Shong, Category Manager, Global Oral Care  
Judith Sills, Pharm. D., Senior Director, U.S. Regulatory Affairs  
and Global Product Safety  
Richard D'Souza, Vice President, R&D, Oral Care,  
Upper Respiratory  
David Long, Associate Council, Regulatory Affairs

and

**Food and Drug Administration**

**Division of OTC Drug Products, HFD-560**

Charles J. Ganley, M.D., Director  
Linda M. Katz, M.D., M.P.H., Deputy Director  
Robert L. Sherman, Review Biologist  
Gerald M. Rachanow, Regulatory Counsel  
Debbie Lumpkins, Team Leader, Microbiologist  
Rosemarie Neuner, M.D., M.P.H., Medical Officer  
Cazemiro R. Martin, Review Chemist  
Stephanie Mason, IDS Reviewer  
Kerry Rothschild, Project Manager

**Division of Dermatologic and Dental Drug Products, HFD-540**

Frederick N. Hyman, D.D.S., M.P.H., Dental Reviewer

**Other Attendees**

Patrice B. Wright, Ph.D., Director, Pharmacology & Toxicology,  
Consumer Healthcare Products Association  
Carrie Hay Gregory, Manager, Legal & Regulatory Affairs, CTFA  
Michael Fagan, Public Relations, New York  
Sybil Mead, News Editor, The Rose Sheet, FDC Reports

**Subject:** Oral Health Care

**Purpose:** To reach agreement on the regulatory process to market  
a combination drug product making both anticaries and  
antiplaque/antiginivitis claims.

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Paul Okarma opened the meeting with a brief discussion of a discrepancy between the dosing for oral rinses in the anticaries final monograph and the Dental Plaque Subcommittee's (the Subcommittee) recommended **dosing** for antigingivitis, antiplaque oral rinses in that ongoing rulemaking. Dr. Okarma stated that Warner-Lambert wishes to market a combination mouthrinse product making anticaries and antiplaque/antigingivitis claims. He noted that the Subcommittee had agreed that an anticaries agent combined with an antiplaque/antigingivitis agent would be a rational combination.

Dr. Okarma stated that Warner-Lambert would submit a study supporting amendment of the anticaries final monograph to allow for a dosing regimen for **fluoride** mouthrinses consistent with the Subcommittee's recommended dosing for antiplaque/antigingivitis mouthrinses. If the agency agrees that the alternative **dosing** is safe and effective, Warner-Lambert requests that the agency issue a notice of enforcement policy permitting interim marketing of the combination product during the period it takes to formally amend the anticaries final monograph.

Discussion points:

Citing previous examples of published notices of enforcement policy, Warner-Lambert requested agreement on a regulatory process that would allow the interim marketing of a combination anticaries and antiplaque/antigingivitis mouthrinse product. This process would permit marketing of the combination mouthrinse during the time period necessary to amend the anticaries final monograph to allow a dosing regimen consistent with the Subcommittee's recommended dosing for antiplaque/antigingivitis mouthrinses.

Warner-Lambert noted that the Subcommittee had found the ingredients in Listerine Mouthrinse to be safe and effective and had agreed that an anticaries agent combined with an antiplaque/antigingivitis agent would be a rational combination. Warner-Lambert agreed to submit data and petition to amend the anticaries final monograph, but declined to discuss the details of any studies at this meeting.

Agency representatives responded to the following questions:

1. Once the studies supporting an additional dosing regimen are reviewed and accepted, will the agency agree to publish an enforcement policy allowing marketing of a combination mouthrinse product during the period that it takes to formally amend the anticaries monograph?

**Agency response:**

With no information concerning studies that the sponsor plans to submit to support amendment of the anticaries monograph, the agency cannot make any commitments regarding future actions at this time. Although a potential pathway to market the combination mouthrinse could be a notice of enforcement policy, the agency recommends that the sponsor follow the established procedure and submit a citizen petition including data supporting amendment of the anticaries monograph to include an **additional** dosing regimen for oral rinses and allow for the marketing of **an** anticaries and antiplaque/antigingivitis mouthrinse.

Although the sponsor cites a 1992 enforcement policy allowing marketing of a combination tooth desensitizer/anticaries product, neither the oral healthcare nor anticaries monographs were final rules at that time. Because the anticaries monograph is a final rule, amendment of the monograph would not necessarily require more time than the notice and comment period required before publication of an enforcement policy to allow interim marketing.

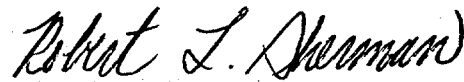
2. The Panel recommended that an antiplaque/antigingivitis agent plus an anticaries agent would be a rational combination product. Does the agency agree that this is an acceptable combination?

**Agency response:**

Although the Panel, without any data, agreed in principle that an antiplaque/antigingivitis agent plus an anticaries agent would be a rational combination, **the** agency is still assessing that recommendation. The agency currently has no data on the safety and effectiveness of the proposed combination. The first step in marketing such a combination product would be to establish that the proposed combination is generally recognized as safe and effective.

Agreements:

1. The sponsor will submit data to support amendment of the anticaries final monograph to include an additional dosing regimen for fluoride mouthrinses and to allow for a combination product making antiplaque/antigingivitis and anticaries claims.
2. The sponsor will request a feedback meeting to obtain agency comments on any submitted protocols.

A handwritten signature in cursive script, reading "Robert L. Sherman".

Robert L. Sherman  
Meeting Chairperson